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IMPROVEMENTS IN AND RELATING TO RETENTION APPARATUS

TECHNICAL FIELD

This invention relates to improvements in and relating to retention apparatus.

It is envisaged the retention apparatus will be most commonly used to retain a
5 substance delivery device in a passage or body cavity of an animal.

In particular, the retention apparatus will be most commonly used in situations for retaining a substance delivery device in a body cavity that can be readily accessed, such as the vagina, uterus, rectum, and so forth.

The retention apparatus is designed to maintain the substance delivery device in said
10 cavity for predetermined periods to enable substances in the delivery device to be delivered into the animal in a manner (controlled or otherwise) over the required period of time.

Such substance delivery devices may be used to control the release of substances into the animal for controlling parasites, release of nutritional supplements, for
15 vaccines, for controlling reproduction and/or growth and so forth as part of a programme involving chemical and/or hormonal intervention.

BACKGROUND ART

A range of retention apparata is available in the prior art for use in retaining associated apparatus in or on an animal for a required time period. The retention
20 apparatus may be included on or be attachable to the apparatus.

Retention apparata for retaining a device within a passage or body cavity of an animal may be fully (along with the device) or partially inserted into the animal. To facilitate insertion of the device and retention apparatus the retention apparatus may be compressible. Once inserted, the retention apparatus typically resumes its
25 uncompressed configuration thereby retaining the device to which it is attached within the animal's body cavity.

Such retention apparata may be an integral part of the device as with compressible helical coils, or the devices may include multiple lobes or arms affixed to a device. The latter types of retention apparata rely on the ability to fold the lobes or arms onto
30 each other to facilitate insertion of the device into the body cavity of the animal. Alternately the lobes or arms may be flexed or hinged to a position where they are substantially in line with the device to which they are attached for easy insertion of

the device into the animal's body cavity. Once inserted the compressed coil, lobes or arms spring open to retain the device inside the animal's body cavity.

However, a number of problems exist with the use of such retention apparatus. For example, apparatus that expands once inserted into the body cavity of an animal can

- 5 a) cause irritation to the walls of the cavity and discomfort to the animal. Whilst retention apparatus allow retention of the device within the animal's body cavity, movement of the device within the cavity is also typically permitted. This movement can lead to internal irritation of the cavity (and cervix if the cavity is the vagina of the animal) and cause discomfort to the
- 10 animal,
- b) impact detrimentally on the flow of the animal's internal body secretions,
- c) be difficult to extract from the animal's body cavity once the functional utility of the device to which they are attached has been exhausted, and
- d) be problematic to insert into the animal's body cavity in the first instance
- 15 due to the nature of the material from which the retention apparatus are made and therefore
- e) require a separate applicator to facilitate insertion of the device and the retention apparatus into the animal's body cavity, and.
- f) often be suitable only for use in small body cavities

20 Alternatively, in some prior art retention systems, the retention apparatus may itself be impregnated with, or contain, the substances required to be delivered into the animal's body cavity. With time, secretion of the substance into the body cavity can effectively reduce the surface area of the retention apparatus and in turn reduce the ability of the retention apparatus to retain the substance delivery device in the

25 animal's body cavity. Accordingly, muscular contractions of the walls of the animal's body cavity may force the device and its retention apparatus out of the animal's body cavity before complete delivery of the substance(s) has been achieved. Therefore, the effectiveness of the substance delivery device may be severely limited.

30 Systems requiring the use of applicators to insert the devices and their retention apparatus into the body cavity of the animal also have a number of disadvantages. The applicators may be complex, bulky, and costly to manufacture, or may increase the time taken for insertion of a substance delivery device into an animal.

It would therefore be advantageous to have a retention apparatus capable of being

35 used with a device for insertion into an animal's body cavity that:

- (a) effectively retains that device within the cavity for the required period: and
- (b) enables the delivery device to be easily inserted and removed; and yet

- (c) does not detrimentally impact on the normal body processes (such as by impeding flow of body secretions and so forth) by its mere physical presence; and
- 5 (d) is suitable for use with devices to be inserted into body cavities such as the vagina, uterus and rectum (principally); and
- (e) can be used without causing undue physical discomfort to the animal; and
- (f) can easily be adapted for use with a range of animal species,
- (g) does not require a specialised applicator.

10 It is an object of the present invention to address the foregoing problems or at least to provide the public with a useful choice.

Further aspects and advantages of the present invention will become apparent from the ensuing description, that is given by way of example only.

DISCLOSURE OF INVENTION

15 According to one aspect of the present invention there is provided retention apparatus capable of retaining a substance delivery device within a body cavity of an animal into which the substance delivery device is inserted, the retention apparatus including

positioning apparatus capable of maintaining the substance delivery device in a preferred position within the body cavity of an animal, and

20 restraining apparatus capable of hindering unwanted removal of the positioning apparatus and the substance delivery device from the animal's body cavity,

characterised in that at least a portion of the restraining apparatus is attached in a preferred location on the external surface of the animal's body via attachment means.

25 According to another aspect of the present invention there is provided retention apparatus substantially as described above wherein at least a portion of the positioning apparatus is inserted into the animal.

30 According to another aspect of the present invention there is provided retention apparatus substantially as described above wherein the positioning apparatus also includes engaging apparatus capable of engaging with either or both a portion of the restraining apparatus and the substance delivery device.

According to another aspect of the present invention there is provided retention apparatus substantially described above wherein the restraining apparatus is comprised of resilient material capable of being stretched to effect the required

tension to maintain the positioning apparatus and the substance delivery device substantially within the animal's body.

According to another aspect of the present invention there is provided retention apparatus substantially described above wherein the restraining apparatus includes a
5 substantially elongate portion and a substantially expanded portion.

According to another aspect of the present invention there is provided retention apparatus substantially described above wherein the attachment apparatus is a contact adhesive capable of being applied to either one or both of the expanded portion of the restraining apparatus and the external surface of the animal's body.

10 In this specification unless the context otherwise states, the term positioning apparatus shall mean and refer to any apparatus that is capable of positioning the substance delivery device in a preferred position within an animal's body cavity.

For ease of reference the positioning apparatus shall now be referred to as a tail rod. However, it should be appreciated that use of this term is not to be seen as limiting.

15 The term restraining apparatus in this specification shall mean (unless otherwise stated) any apparatus capable of maintaining at least the tail rod in the required position within the animal's body cavity whilst specifically hindering the ability of the tail rod and the substance delivery device attached thereto to work out of the animal's body cavity when the animal is engaged in normal daily activities and/or
20 bodily functions. The animal's activities include but are not limited to normal walking or running movements, mounting of the animal by another animal, defecation, urination, muscular activity within the animal's body cavity into which the substance delivery device has been inserted, and the production by the animal of secretions such as mucus that could operate to lubricate the entry to the animal's
25 cavity and facilitate expulsion of the substance delivery device and the tail rod from the cavity.

For ease of reference the term restraining apparatus shall now be referred to as the tail. It should be appreciated however that use of this term is not intended to limit the specification.

30 The term attachment means in the specification shall mean unless otherwise stated, any apparatus or means of attachment capable of fastening, affixing or joining the restraining apparatus on to or around the external surface of the animal's body.

For ease of reference, the means of attachment shall now be referred to as an adhesive. However, it should be appreciated that this term is not intended to limit

the use of any other suitable means of attachment or apparatus capable of performing the required function as stated above.

5 The substance delivery device referred to in the specification substantially includes a body (or sheath) capable of substantially enclosing all of the components of the substance delivery device. The applicant has described a preferred embodiment of the substance delivery device in New Zealand Patent Specification No. 304150. However, any suitable substance delivery device may be used with the present invention.

10 The substance delivery device preferably is used to deliver at least one therapeutic agent into the animal. The therapeutic agent can include either or both one or more chemicals and hormonal substances. For example the substance delivery device may be used to deliver nutrients, vaccines, breeding hormones, growth hormones, anti-parasitic treatments and so forth. Administration of the agents being achieved by insertion of the substance delivery device into an animal's body cavity, and release
15 of the agents therefrom and into the animal.

In preferred embodiments of the present invention, the tail rod is a substantially solid and rigid rod. A solid rod is preferred to ensure the rod is sufficiently strong enough to withstand wear and tear, particularly when used in the larger domestic animals such as horses and cows.

20 However, in some species of animals, hollow rods may also be suitable.

In preferred embodiments, the tail rod is a single unit. However, in other embodiments the tail rod may be comprised of two or more sections attached to each other to obtain the required length, as needed for the particular animal with which the positioning apparatus is used.

25 The tail rod is preferably rod shaped to provide a smooth outer surface, free of angles or corners that may otherwise cause physical discomfort to the animal or result in irritation of the linings of the animal's body cavity or passages by such sharp edges. In addition, the round rod shape contributes to the ease of insertion of the tail rod into the animal's cavity/passage.

30 Preferably the dimensions of the tail rod are specific to the species of animal with which the tail rod (and the substance delivery device attached to it) is used. In addition, there may be variations in the dimensions of the tail rod for use with animals within the same species due to the age, sex and/or breeding status of the animal into which the tail rod and the substance delivery device are to be inserted.

35 For example, when the substance delivery device is being used as an intravaginal

device for cows, the dimensions of the tail rod will be specifically (and therefore varyingly) designed for older dairy cows, first mated heifers, beef cows and early post-partem dairy cows and so forth. As can be appreciated, the vaginal canal can differ depending on age of the animals within the same species, and also differs
5 between species.

Similarly, where the tail rod may be used with a substance delivery device for insertion into different body cavities (such as the rectum), again the length of the tail rod will understandably vary.

In particular, where the tail rod is used with an intravaginal substance delivery
10 device, the length of the tail rod is critical for ensuring the device is inserted past the pelvic bone of the animal. For example, trials with the retention apparatus having a tail rod inserted at 100mm into the vaginal cavity of mature cows resulted in rotation and expulsion of the device. By comparison, having the tail rod inserted 150mm into the vaginal cavity ensured greater retention of both the tail rod and the substance
15 delivery device within the animal.

In preferred embodiments of the present invention the tail rod is made from substantially rigid material. The applicant has found that use of some polyurethane PVC materials provide too much flexibility to the rod, enabling the rod to be worked
20 out of the animal's body cavity and leading to expulsion of the entire system by the animal. However, it must be appreciated that materials used for the tail rods (and the substance delivery device body) should pose no physiological danger to, cause no allergic reactions in and cause minimal discomfort to the animal.

In addition, the tail rod is preferably configured to include an elongate straight portion. The substantially elongate straight portion is designed to facilitate insertion
25 of the tail rod into the animal's body cavity without causing undue discomfort to the animal. However, an undulating elongate portion may be preferred for use in some cavities and/or passages, or with some animals to ensure optimum retention inside the animal.

The length of the elongate portion is such that it ensures and the attached substance
30 delivery device is also inserted into the animal's body cavity to the required depth.

The tail rod also includes a substantially angled portion at one of its distal ends. This angled portion may operate as a stop to complete insertion of the rod within the animal's cavity/passage. The angled portion operating as a stop by pressing against
35 the outside of the animal adjacent to the cavity/passage entrance. The length of the angled portion may vary depending on the overall anatomy of the animal with which the positioning apparatus is used. In addition, this angled portion of the rod may

vary in configuration when it is used as a stop, to ensure better co-operation of the surface of the angled portion against the animal.

As appreciated, the overall configuration of the tail rod facilitates retention of it and the attached substance delivery device within in the animal's body cavity.

- 5 The opposite distal end (opposite in the angled portion) of the tail rod, is substantially straight. The substance delivery device may be fixedly or removably attached to this straight, distal, end of the substantially elongate straight portion.

Fixed attachment may be achieved by heat moulding the substance delivery device to the end of the substantially elongate portion. However, in preferred embodiments,
10 the tail rod is fixed to the substance delivery device via a one-way engaging system, such as a bayonet system or press fitting system that operates to fix the tail rod to the substance delivery device in a non-removable manner.

In yet other embodiments, the substance delivery device and the tail rod may be moulded in one piece to obviate problems of the substance delivery device becoming
15 detached from the tail rod.

Alternatively, in other embodiments, the substance delivery device may be removably attached to the tail rod to enable the tail rod to be used repeatedly, simply by replacing an expended substance delivery device with a new one.

Such removable attachment of the substance delivery device to the tail rod may be
20 effected through engaging a complementarily configured section at the end of the substantially elongate portion of the tail rod with a corresponding section on the substance delivery device. Such configuration could include a threaded, bayonet or other suitable system.

Alternately, a portion of the substance delivery device may simply be inserted into
25 the end of the tail rod and pinned in position. For example, insertion of a locking pin into an appropriately located aperture on the external surface of the tail rod which can be aligned with a similarly located aperture on the inserted portion of the substance delivery device. As can be appreciated, any suitable arrangement for attaching the tail rod to the substance delivery device may be employed with this
30 invention as required.

The substantially angled distal end of the tail rod is preferably configured to receive a portion of the restraining apparatus. For ease of reference the restraining apparatus shall now be referred to as a tail. However, use of this term is not to be seen as limiting.

In preferred embodiments, the substantially angled portion includes a series of barbs integrally moulded into the tail rod. These projecting barbs are capable of being received into, or are capable of receiving, a complementarily configured portion of the tail.

- 5 The arrangement is designed to be a quick fit system to enable easy attachment and removal of the tail onto and from the tail rod. However, it can be appreciated that in other embodiments of the present invention, any suitable means of attaching the tail to the substantially angled portion of the tail rod may be used with this invention.

- 10 In addition, in some embodiments it may be preferred that the tail rod and the tail be a single structure ready for attachment to the substance delivery device.

Alternatively, the entire combination of the tail, tail rod and substance delivery device may be moulded in one piece for devices that are to be thrown away after use. On the other hand, individual tails, tail rods and substance delivery devices may be preferred where re-use of the individual sections is required or desired.

- 15 In preferred embodiments of the present invention the tail includes a substantially elongate portion and a substantially expanded portion. The expanded tail portion is located towards one distal end of the elongate portion of the tail, whilst the other distal end the elongate portion is configured to attach (either fixedly or removable) to the angled portion of the tail rod.

- 20 For ease of reference, the substantially elongate portion shall be referred to as a strap and the substantially expanded portion shall be referred to as a patch. However, it should be appreciated that the use of either of these terms is not intended to limit the scope of the specification.

- 25 Preferably, the length of the strap is dictated by the species of animal with which the retention apparatus is being used. In addition, the length will also be dictated by the age and sex of the particular animal.

- Similarly, the width of the strap is also dictated by a number of factors including the ability of the strap to perform the required function in relation to the retention apparatus without interfering with the normal bodily functions of the animal, or causing undue discomfort to the animal.
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- In addition, the tail is required to be made of substantially flexible material. The material is preferably soft/supple enough to be able to be moulded to conform to the external shape of the animal against which the strap rests again without interfering with the bodily functions of the animal and without causing unnecessary discomfort to the animal.
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Preferably, the restraining apparatus is also made of resilient material capable of being stretched to effect the tension required to maintain the tail rod and substance delivery device within the animal's body cavity whilst also being firmly attached at a suitable location to the exterior surface of the animal's body.

- 5 Preferably therefore, the tail is made of a rubber material of a particular formulation to provide the required resilience, flexibility and durability, without causing any adverse physiological reactions in (such as allergic reactions) or physical discomfort to the animal with which it is used.

10 However, any suitable material may be adapted for use with the invention. For example, early prototypes included plastic and/or metal wires capable of being bent to conform to and be moulded against the animal's body. However, wires, whilst capable of being used, have limitations in terms of their resilience.

15 In some embodiments, the tail is made from layers of the preferred rubber material that is laminated. Preferably the strap includes a greater number of laminated layers than the patch. Multiple layers can increase the strength of and contribute to the required resilience of the strap. The patch is preferably thinner to enable the patch to be flexible enough to be secured to the animal's external surface by the attachment apparatus.

20 In preferred embodiments however, the tail is injection moulded using the specific rubber material to produce a tail in which the stem is substantially thicker than the patch (which essentially looks like a paddle), but where the entire tail is produced in one procedure. Alternately, the tail may be stamped/cut from sheet material having the required properties and thickness in the strap and patch areas.

25 The resilience of the material is also such that it is capable of being stretched to effect the required tension when the strap is attached to the animal. Yet at the same time the strap is flexible enough to enable the strap of the tail to be moulded to conform to the shape of the animal's external body surface without interfering with the animal's normal bodily functions. For example where the retention apparatus is used with an intravaginal device, the tail is moulded to conform to the shape of the
30 cow without interfering with the function of the cow's tail, or with the animal's defecation or urination. In addition, the tail is able to fit closely to the perineum to prevent faecal matter from gaining ingress to the vaginal cavity.

As can be appreciated, whilst the tail is required to be made of substantially resilient and flexible material, it is preferable that the material demonstrate a firm elasticity to
35 prevent over-stretching of the tail. Over-stretching of the tail could enable the tail rod to rotate and be expelled from the animal's body cavity.

In preferred embodiments of the present invention, the patch is required to be of a sufficient surface area to ensure secure attachment of the tail to the animal's body. Accordingly, the patch of the tail is substantially circular. The applicant has experimented with a range of shapes for the patch portion of the tail, and whilst
5 other shapes may be used, the circular patch is preferred. This overall configuration of the patch has been found to be critical to the success of attachment of the patch to the external surface of the animal's body.

The dimensions of the strap and/or patch may also be adjustable to enable the tail to be used on animals of different ages, sexes and so forth. For example, the tail used
10 for cows may be different to that used for heifers or young stock, and so forth. Therefore, to accommodate the differing requirements, the patch and strap may be two separate portions that may be joined together as required. Such an embodiment may also include adjustment apparatus to facilitate adjustment of the tail for use with a particular animal. Alternatively, one-piece systems may also include such
15 adjustment apparatus.

In addition, the material of the tail is required to be sufficiently strong to obviate against the tail breaking/snapping. The substantially thicker strap contributes to providing the required strength.

In preferred embodiments of the present invention where the retention apparatus is used for an intravaginal, intrarectal and so forth substance delivery device, the patch
20 is preferably attached in the region of the animal's tail but to one side of the animal's backbone.

Preferably the point of attachment is located between the backbone and the pin bone (ischium) of an animal, such as a cow. This positioning enables the tail to be
25 attached to the animal's external surface whilst providing sufficient tension to maintain the tail rod in the body cavity without the retention apparatus interfering with other bodily functions of the animal such as urination and so forth (depending upon the cavity into which the substance delivery device is inserted).

In preferred embodiments of the present invention, the patch is attached to the external surface of the animal's body by the means of attachment. Preferably the
30 means of attachment is an adhesive.

In preferred embodiments, the means of attachment is a contact adhesive that is fast curing and capable of being used on animals with minimal (if any) detrimental effects or discomfort. Accordingly, the contact adhesive is anti-allergenic,
35 physiologically safe and so forth.

In addition, the adhesive is one that is preferably capable of attaching the patch to the animal's external surface irrespective of the animal's hair or fur type, or length. However, attachment of the patch to the animal's external surface may be affected by external conditions, such as material on which the animal beds down, or rolls in.

5 Where the ground or bedding material is dusty and/or sandy, the animal's body may need to be shaved in the region where the patch is to be attached. Optionally, the area may also be cleaned with a suitable fluid (such as a solvent, or a burst of air, and so forth), to further reduce the amount of material on the animal's skin that may affect the ability of the patch to adhere thereto. However, there are typically no

10 long term effects of attaching the patch by adhesive to the animal's skin, as regrowth of hair prevents permanent damage to the skin from adhesives, when the patch is removed.

The applicant has trialled a range of adhesives such as MULTIGRASS (supplied by Bostik) and KAMAR with varying degrees of success. However, the preferred

15 adhesive is adapted to meet the applicant's objectives which are to use an adhesive compatible with both the animal and the preferred material used for the patch, whilst also providing a very fast cure.

One of the advantages of using the preferred contact adhesive in the attachment of the tail to the external surface of the animal is that the substance delivery device can

20 be inserted into the animal's body cavity and the retention apparatus secured in place with minimal time and effort but with maximum retention of the substance delivery device in the animal's body cavity for the period required to complete the program of treatment of the animal with the appropriate therapeutic agent.

The application of the adhesive to the patch and/or the animal may vary however,

25 depending upon the type and length of the animal's hair or fur. In any situation a successful patch/animal bond is essential.

Accordingly, the adhesive may be applied to the animal only, the patch only, the patch and the animal and so forth. Where applied only to the animal or only to the patch, the patch is temporarily pressed on to the attachment area, removed, left for a

30 short period and then re-applied to the attachment area to enable the adhesive to bond.

The adhesive may be pre-applied to the patch during manufacture of the retention apparatus. The adhesive may then be covered by a removable material to prevent the patch sticking to objects before required. At the time the patch is to be applied to

35 the animal the material is peeled from the surface of the patch to expose the adhesive, ready of use.

It can be appreciated that different adhesives, or means of attachment of the patch to the animal may be required depending on the species of animal with which the retention apparatus is used. For example, attaching the patch to animals with woollen coats may pose different problems than where the patch is attached to animals with hair, and so forth.

Accordingly, the patch may be secured via other means. For example, contact tapes, bubble patches containing adhesive that is released when the bubbles are burst (on contact with the animal, or when pressure is applied), and so forth may be used.

The present invention has been developed specifically for retaining a substance delivery device in the body cavity of an animal by employing restraining apparatus capable of being attached between the back bone and the ischium (pin bone) of a domestic animal. Trials on cows suggest the invention will be equally effective in all cow types. This concept has been developed to remedy observed deficiencies in other retention systems for such substance delivery devices.

Systems that include villi, lobes or arms for retaining the substance delivery device within the body cavity of an animal have been found to be deficient. For example, typical villi systems generate the production of significant quantities of mucus, that have been observed at the time of removal of the device.

In addition, plugs of mucus may also be found following the removal of the device from (for example) the vaginal cavity. Where such substance delivery devices have been used intravaginally, mucus production is due to the interaction of the villi with the sensitive vaginal mucosa and from irritation of the cervix by the front of the device. In addition, villi systems whilst retaining the device intravaginally, nevertheless enables the device to move backwards and forward within the vagina.

The production of large quantities of mucus and occasionally blood is typically due to the substance delivery device contacting and irritating the cervix. The production of large quantities of mucus (and blood) is unacceptable, as it indicates undesirable interference to the animal by the device.

The present retention system is designed to reduce mucus production, as it is less invasive and provides less opportunity for the device to contact the cervix and therefore reduces interference of the cervix by the device.

To achieve maximum effectiveness of the retention apparatus, the depth of insertion of the tail rod, the location of the patch on the animal, the patch/animal bond, and the tightness of the tail strap are all important factors, as is minimal trauma to the animal

at any stage during the treatment programme (when the substance delivery device is intra animal).

BRIEF DESCRIPTION OF DRAWINGS

5 Further aspects of the present invention will become apparent from the following description that is given by way of example only and with reference to the accompanying drawings in which:

Figure 1 is a diagrammatic side view of the restraining apparatus in accordance of one preferred embodiment of the present invention, and

10 Figure 2a is a diagrammatic plan view of the restraining apparatus in accordance with one preferred embodiment of the present invention, and

Figure 2b is a diagrammatic cross-sectional view through the strap of the restraining apparatus in accordance with one preferred embodiment of the present invention, and

15 Figure 3a is a diagrammatic side view of the restraining apparatus in accordance with another preferred embodiment of the present invention, and

Figure 3b is a diagrammatic cross sectional view through the distal end of the restraining apparatus configured to receive or be attached to the positioning apparatus of the retention apparatus in accordance with one preferred embodiment of the present invention, and

20 Figures 4, 5 are diagrammatic bottom and top plan views respectively of the restraining apparatus in accordance with another preferred embodiment of the present invention, and

25 Figures 6a, 6b are diagrammatic side views of the positioning apparatus of the retention apparatus in accordance with one preferred embodiment of the present invention, and

Figure 6c is a diagrammatic top plan view of the positioning apparatus in accordance with one preferred embodiment of the present invention, and

30 Figures 6d, 6e are diagrammatic representations of the angled distal portions of the positioning apparatus, configured to engage with the substance delivery device and the restraining apparatus, respectively, in accordance with one preferred embodiment of the present invention, and

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Figure 7 is a diagrammatic representation of an early prototype of the retention apparatus attached to a substance delivery device in accordance with another embodiment of the present invention, and

Figure 7b is a diagrammatic representation of a preferred embodiment of the retention apparatus attached to a substance delivery device.

BEST MODES FOR CARRYING OUT THE INVENTION

With reference to the diagrams by way of example only there is provided retention apparatus, generally indicated by arrow 1, as shown in Figures 1 through 7 for retaining a substance delivery device (generally indicated by arrow 2) within a body cavity of an animal (not shown) into which the substance delivery device (2) is inserted.

The retention apparatus (1) includes positioning apparatus, generally indicated by arrow 3. The positioning apparatus (3) is capable of maintaining the substance delivery device (2) in a preferred position within the body cavity of the animal.

The retention apparatus (1) also includes restraining apparatus, generally indicated by arrow 4, for hindering removal of the positioning apparatus (3) and the substance delivery device (2) from the animal's body cavity.

The retention apparatus (1) also allows for a means of attachment, (generally indicated by arrow 5) for attaching a portion of the restraining apparatus (4) in a preferred position on the external surface of the animal's body.

The substance delivery device (2) is configured to be inserted into an animal's body cavity to release therapeutic agent(s) into the animal, for a pre-determined period. The substance delivery device (2) is represented in Figures 6c and 7. However, it should be appreciated that the structural configuration of the substance delivery device (2) can vary.

As can be seen in Figure 7 the substance delivery device (2) is substantially integrally attached to the positioning apparatus or tail rod (3). In Figure 6a the substance delivery device (2) can be adapted such that the tail rod (3) may be fixedly or removably attached to the substance delivery device (2).

The tail rod (3) is appropriately dimensioned in terms of width and length to enable the substance delivery device (2) to be inserted into the animal's body cavity to a depth that prevents the tail rod (3) and the substance delivery device (2) from rotating and being expelled from the animal's body cavity during the animal's normal bodily functions (such as muscular contractions) and/or general physical activities (such as bulling in cows and so forth).

As shown in Figures 6a-e the tail rod (3) is a substantially circular rod with an elongate portion (6) and a substantially angled portion (7). The substance delivery device (2) is attached to the appropriately configured distal end (8) of the substantially elongate portion (6) of the tail rod (3), whilst the substantially angled portion (7) is configured at (9) to receive a portion of the restraining apparatus or tail (4).

The tail rod illustrated is substantially circular and smooth to facilitate easy insertion of the substance delivery device (2) and the tail rod (3) into the animal's body cavity without causing undue irritation to the walls of the body cavity or the entry passage, or cause undue discomfort to the animal, during the insertion, withdrawal or retention period.

The tail rod (3) in Figure 7 also includes flexible joints (10) to enable the tail rod (3) to conform to the required shape to facilitate configuration of the tail rod (3) for the animal with which it is used.

Figure 7 representing an earlier prototype illustrates, the restraining apparatus or tail (4) comprising a wire tail (16) and a plastic tail (17), both of which are fed through the tail rod (3). However, later preferred embodiments of the tail (4) as illustrated in Figures 1-5 inclusive, are made of a substantially resilient and flexible rubber material to enable the tail (4) mould to the external surface of the animal as required to enable the tail (4) to effectively restrain the tail rod (3) and the substance delivery device (2) from being expelled from or working out of the animal's body cavity.

The tail (4) includes a strap (11) and a patch (12). The strap (11) is substantially elongate, the length being dictated by either or both the species of animal with which it is to be used and the age of the animal. The patch (12) is substantially circular and substantially thinner than the strap (11) portion of the tail (4) (as shown in Figures 1 through 5).

The dimensions and/or configuration of the patch (12) are critical to ensuring successful attachment of the patch (12) to the external surface of the animal's body.

The patch (12) is positioned towards one distal end (13) of the strap (11). The opposite distal end (14) of the strap is configured at (18) to complement and be attached to the configured distal end (9) of the tail rod (3).

In use, the retention apparatus (1) is either integral with the substance delivery device (2) or is attached to the substance delivery device (2) for use.

It should be appreciated that the substance delivery device (2), the tail rod (3) and the tail (4) may be either moulded in one piece. Alternatively, one or more of the

substance delivery device (2), the tail rod (3) and the tail (4) may be separate from or attached to, an adjacent portion depending upon the requirements of the retention apparatus (1) and the substance delivery device (2).

5 For example, where the retention apparatus (1) and the substance delivery device (2) are designed to be discarded after use, all three features may be moulded as one piece. Alternately, where the tail rod (3) and/or the tail (4) can be re-used or interchanged, accordingly, they are preferably configured to be capable of inter-connection to the other apparatus.

10 Figures 1 to 5 illustrate embodiments of the tail (4). Figures 1 and 3b show the distal end (14) of the strap where it is configured at (18) to receive an appropriately configured portion of the tail rod (3).

Figure 2b further illustrates a cross-sectional view through the strap (11) having a preferred configuration. As can be seen, the strap (11) portion of the tail (4) differs in thickness to the patch (12).

15 The means of attachment (5) in preferred embodiments is a preferred contact adhesive capable of being used with animals. However, any suitable adhesive may be used with the retention apparatus provided it is effective at maintaining contact between the patch (12) and the external surface of the animal's body throughout the period of treatment. Treatment periods may be relatively short (up to a few days) or
20 may be considerably longer (several weeks).

While adhesive (5) is the preferred means of attachment, nevertheless, other embodiments of the invention may incorporate other attachment apparatus specifically designed for different species of animals where adhesive may be unsuitable.

25 Both the substance delivery device (2) and the tail rod (3) are inserted into an animal's body cavity such as the vaginal cavity, the rectal cavity and so forth into which a therapeutic agent(s) is required to be delivered.

The tail rod (3) is inserted to a depth where it optimally contributes to maintaining the substance delivery device (2) within the animal's body cavity. At the same time
30 the tail rod (3) may protrude only so far (or not at all) to ensure effectiveness of the tail (4) - providing the tail rod (3) does not catch on any part of the cow's anatomy (such as the tail) or is not capable of being contacted by another animal or by environmental objects that may cause movement of the tail rod (4) and the substance delivery device (2) within the animal's body cavity, or may contribute to the
35 substance delivery device being expelled from the animal's body cavity.

When the substance delivery device (2) and the tail rod (3) have been inserted into the animal's body cavity, the strap (11) of the tail (4) is stretched to create sufficient tension to enable the strap (11) to mould or conform to the shape of the body of the animal without interfering with the animal's bodily functions. For example, the
5 strap (11) is stretched to provide sufficient tension to maintain the tail rod (3) in position whilst not impeding the function of the animal's tail, or the bodily functions of defecation or urination.

Preferably, where the retention apparatus (1) is used with an intravaginal device (2), the strap (11) of the tail (4) is positioned to sit closely to the animal's perineum to
10 prevent faecal matter from gaining ingress to the vaginal cavity.

Preferably, where the substance delivery device (2) and the retention apparatus (1) is used to administer therapeutic agent(s) into the vagina of an animal such as a cow, the tail (4) holds the tail rod (3) firm and ensures the intravaginal device (2) remains securely in the vagina by ensuring appropriate tension of the strap (11) and
15 attachment of the patch (12) to the cow's back between the back bone and the ischium (pin bone).

As can be appreciated, the point of attachment on the animal's external surface will depend upon the body cavity with which the substance delivery device (2) and the retention apparatus (1) are used.

20 The adhesive (5) is then applied to either or both the patch (12) and the external surface of the animal's body. After the required period of time to allow the adhesive to bond with the surface onto which it has been applied, the patch (12) is then pressed onto the glue patch on the animal's body. The patch (12) is held in position for sufficient time to ensure bonding between the patch (12) and the animal's body.

25 It should also be appreciated that the dimensions and configuration of the substance delivery device (2), the tail rod (3) and the tail (4), as well as the type of attachment apparatus (5) will depend largely upon the species of animal with which the apparatus is used. The age and sex of the animal will also be factors to consider. Similarly, it may be necessary to use different materials for both the tail rod (3) and
30 the tail (4) as required to ensure effectiveness of the retention apparatus (1) with different species of animals.

Aspects of the present invention have been described by way of example only and it should be appreciated that modifications and additions may be made thereto without departing from the scope thereof as defined in the appended claims.

THE CLAIMS DEFINING THE INVENTION ARE:

1. Retention apparatus capable of retaining a substance delivery device within either or both a body cavity of an animal and a passage leading thereto into which the substance delivery device is inserted, said retention apparatus including:

positioning apparatus capable of maintaining the substance delivery device in a preferred position within the body cavity and/or passage of the animal, and

restraining apparatus attachable to the positioning apparatus and capable of hindering unwanted removal of the positioning apparatus and the substance delivery device from the animal's body cavity and/or passage,

the retention apparatus characterised in that at least a portion of the restraining apparatus is attachable in a preferred location on the external surface of the animal's body via use of attachment means.
2. Retention apparatus as claimed in claim 1 wherein at least a portion of the positioning apparatus is inserted into either or both the animal's body cavity and a passage leading to the animal's body cavity.
3. Retention apparatus as claimed in claim 2 wherein the positioning apparatus is made from substantially rigid material to prevent the positioning apparatus working out of either or both the animal's body cavity and the passage and thus preventing expulsion of the substance delivery device attached thereto by the animal.
4. Retention apparatus as claimed in claim 3 wherein the material used for the positioning apparatus is anti-allergenic, and shaped to avoid physiological damage and discomfort to the animal.
5. Retention apparatus as claimed in claim 4 wherein the positioning apparatus is shaped to include a substantially elongate portion and a substantially angled portion that, in use, are attached to the substance delivery device and the restraining apparatus, respectively.
6. Retention apparatus as claimed in claim 5 wherein the configuration of either or both the elongate portion and the angled portion are determined by at least one of the animal's species, age, sex and breeding status.

7. Retention apparatus as claimed in claim 6 wherein the substantially elongate portion is configured, including the dimensions of length and/or width, to complement the anatomy of either or both the passage and the body cavity of the animal in to which the positioning apparatus is inserted.
8. Retention apparatus as claimed in claim 7 wherein the length of the elongate portion when used with an intravaginal substance delivery device for insertion into a cow, enables the substance delivery device to be inserted into the vagina such that the leading end of the substance delivery device is positioned anterior to the pelvic bone of the animal.
9. Retention apparatus as claimed in claim 8 wherein the elongate portion attached to an intravaginal substance delivery device for insertion into a cow, is approximately 150mm in length.
10. Retention apparatus as claimed in claim 5 wherein the positioning apparatus optionally includes flexible joints to enable it to be configured to include at least a substantially elongate portion of the shape to complement the anatomy of either or both the passage and the cavity of the animal with which it is used.
11. Retention apparatus as claimed in claim 5 wherein the substantially angled portion of the positioning apparatus rests against the exterior of the animal to facilitate retention of the elongate portion and attached substance delivery device within either or both the animal's body cavity and the passage leading thereto.
12. Retention apparatus as claimed in claim 5 wherein either or both the substantially elongate portion and the substantially angled portion of the positioning apparatus optionally include engaging apparatus to engage with either or both a portion of the restraining apparatus and the substance delivery device.
13. Retention apparatus as claimed in claim 12 wherein the engaging apparatus enables the elongate portion of the positioning apparatus to be either fixedly or removably attached to the substance delivery device.
14. Retention apparatus as claimed in claim 13 wherein removable attachment of the positioning apparatus to the substance delivery device is effected via any one of a bayonet fitting, a push fitting, a screw threaded fitting, and locking pins.

15. Retention apparatus as claimed in claim 13 wherein fixed attachment of the positioning apparatus to the substance delivery device is effected via a one way, non-reversible, push fit system.
16. Retention apparatus as claimed in claim 5 wherein attachment of the positioning apparatus to the substance delivery device is optionally effected via the positioning apparatus and the substance delivery device being a one piece unit to obviate detachment of the positioning apparatus from the substance delivery device.
17. Retention apparatus as claimed in claim 12 wherein the engaging apparatus of the substantially angled portion of the positioning apparatus facilitates the fixed or removable attachment of the restraining apparatus thereto.
18. Retention apparatus as claimed in claim 17 wherein the engaging apparatus of the substantially angled portion of the positioning apparatus includes multiple barbs capable of being received into, or capable of receiving a complementary configured portion of the restraining apparatus.
19. Retention apparatus as claimed in claim 5 wherein the restraining apparatus is integrally connected to the positioning apparatus as a single structure for attachment to or as integrally attached to the substance delivery device.
20. Retention apparatus substantially as claimed in claim 1 wherein the restraining apparatus includes a strap portion and a patch portion.
21. Retention apparatus substantially as claimed in claim 20 wherein in use, the strap portion of the restraining apparatus is attached to the positioning apparatus and rests against the exterior of the animal's body, and the patch portion is attached to the external body surface of the animal.
22. Retention apparatus as claimed in claim 21 wherein the strap portion of the restraining apparatus is configured, including the length, to complement at least one of the age, sex, and species of animal with which the retention apparatus is used.
23. Retention apparatus as claimed in claim 22 wherein at least the strap portion is comprised of resilient material.
24. Retention apparatus as claimed in claim 23 wherein the strap portion is resilient to effect, in use, tension on the positioning apparatus to maintain the positioning apparatus and the substance delivery device substantially within the animal's body passage and/or cavity.

25. Retention apparatus as claimed in claim 24 wherein the resilient strap portion also conforms, in use, to the shape of the animal's body against which the strap portion rests, without the strap portion interfering with the normal bodily functions of the animal or causing discomfort to the animal.
26. Retention apparatus as claimed in claim 25 wherein the strap portion of the restraining apparatus when in use with an intravaginal substance delivery device on a cow, rests against the animal's body in a position close to the perineum to prevent entry of faecal matter in to the vaginal cavity.
27. Retention apparatus as claimed in claim 22 wherein the restraining apparatus is optionally a laminated structure including a resilient material to increase the strength of and contribute to the required resilience of the restraining apparatus, whilst also maintaining the flexibility required to conform to the shape of the animal's body.
28. Retention apparatus as claimed in claim 21 wherein the patch portion of the restraining apparatus is dimensioned to provide sufficient surface area to ensure secure attachment of the patch portion to the external surface of the animal's body.
29. Retention apparatus as claimed in claim 28 wherein the patch portion of the restraining apparatus as substantially circular.
30. Retention apparatus as claimed in claim 20 wherein the patch portion and the strap portion of the restraining apparatus are optionally two separate portions capable of being joined together.
31. Retention apparatus as claimed in claim 30 and claim 22 wherein the patch portion is attachable to a strap portion of any length to effect the preferred configuration of the restraining apparatus as required to complement the particular animal with which the retention apparatus is used.
32. Retention apparatus as claimed in claim 31 wherein the required length of the strap portion for use with a particular animal is optionally achieved by inclusion of adjustment apparatus in the strap portion.
33. Retention apparatus as claimed in claim 21 wherein the patch portion of the restraining apparatus is attachable to an animal's external body surface in the region of the animal's tail, but to one side of the animal's back bone.

34. Retention apparatus as claimed in claim 33 wherein the point of attachment of the patch is optimally located between the animal's back bone and the pin bone (icshium) of the animal, particularly where the animal is a cow.
35. Retention apparatus as claimed in claim 34 wherein attachment of the patch portion of the restraining apparatus between the back bone and the icshium of the cow ensures sufficient tension is applied by the strap portion to maintain the positioning apparatus and the substance delivery device in the body cavity of the animal, without the strap portion interfering with the animal's bodily functions, such as urination and defecation where the substance delivery device is a intravaginal device.
36. Retention apparatus as claimed in claim 1 wherein the attachment apparatus is applied to either or both the patch portion of the restraining apparatus and the external surface of the animal's body.
37. Retention apparatus as claimed in claim 36 wherein the attachment apparatus is a contact adhesive.
38. Retention apparatus as claimed in claim 37 wherein the contact adhesive is applied to either or both the animal's external surface and the restraining apparatus in the form of a contact tape, bubble patches containing adhesive, or as a free flowing liquid adhesive.
39. Retention apparatus as claimed in claim 38 wherein either or both the animal's hair or fur is optionally shaved and the exterior surface cleaned prior to application of the adhesive and attachment of the patch portion onto the animal's body surface.
40. Retention apparatus as claimed in claim 39 wherein the contact adhesive is anti-allergenic, physiologically safe, easy to apply and compatible with the material(s) of the restraining apparatus.
41. Retention apparatus as claimed in claim 1 for use with a substance delivery device configured to be inserted into either or both an animal's body cavity or passage leading thereto, to release therapeutic agents therefrom into the animal over a pre-determined period.
42. A method of attaching retention apparatus as claimed in claim 1 to a substance delivery device for insertion into either or both a body cavity of an animal and a passage leading thereto, said method including the steps of:

- a) attaching the elongate portion of the positioning apparatus having the required configuration to complement the anatomy of the animal, to the substance delivery device; and
- b) attaching the substantially angled portion of the positioning apparatus to the resilient strap portion of the restraining apparatus,

the method characterised by either or both the positioning apparatus and the restraining apparatus forming an integral unit with the substance delivery device, or either being removable therefrom for reuse with subsequent substance delivery devices.

43. A method of using retention apparatus to maintain a substance delivery device within either or both a passage and a body cavity of an animal including the steps of:

- a) inserting the substance delivery device and at least a portion of an appropriately configured positioning device attached thereto into the preferred position within the animal's body cavity and/or the passage leading thereto; and
- b) positioning the strap portion of the restraining apparatus against the exterior of the animal's body to conform to the contours thereof; and
- c) determining the position for attachment of the patch portion of the restraining apparatus on the animal's external surface; and
- d) applying attachment means to either or both the patch portion and the preferred position of attachment on the animal's exterior surface; and
- e) applying tension to the strap portion; and
- f) when the required tension is effected in the strap portion to maintain the positioning apparatus and the substance delivery device in a preferred position within the body cavity and/or passage of the animal, affixing the patch portion of the restraining apparatus to the animal's body in the preferred position; and
- g) applying pressure on the patch portion to ensure secure attachment of the patch portion to the animal's body, and

the method characterised by the tension applied by the restraining apparatus attachable to the positioning apparatus hindering unwanted removal of the positioning apparatus and the substance delivery device from the animal's body cavity and/or passage.

44. Retention apparatus substantially as described herein with reference to the contained examples and attached drawings.

45. A method of attaching retention apparatus to a substance delivery device for insertion into either or both a passage and a body cavity of an animal substantially as described herein with reference to the contained examples and the attached drawings.
46. A method of using retention apparatus to maintain a substance delivery device within either or both a passage and a body cavity of an animal substantially as described herein with reference to the contained examples and attached drawings.

ABSTRACT

This invention relates to improvements in and relating to retention apparatus.

The retention apparatus is used to maintain a substance delivery device in a passage or body cavity of an animal for predetermined periods, particularly a cavity that can be readily accessed, including the vagina, uterus, and rectum. Such retention is required where controlled delivery of substances from the delivery device into the animal is desired as part of chemical and/or hormonal intervention programmes. Substances delivered may include anti-parasitic agents, nutritional supplements, vaccines, hormones, and so forth.

The retention apparatus includes positioning apparatus for maintaining the substance delivery device in a preferred position within the body cavity of the animal and restraining apparatus to hinder unwanted removal of the positioning apparatus and the substance delivery device from the cavity.

The invention is characterised by a portion of the restraining apparatus being attached in a preferred location on the external surface of the animal's body via attachment means.

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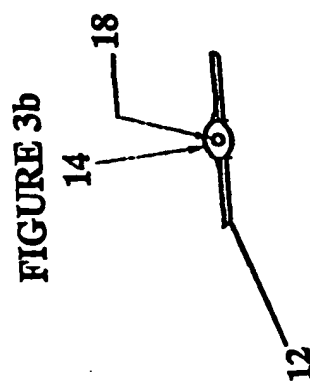
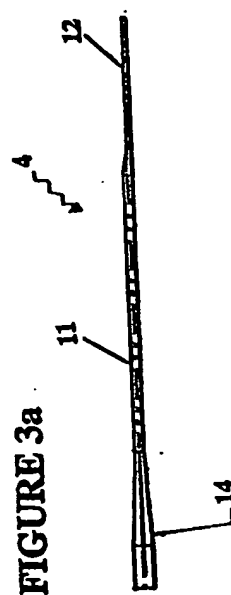
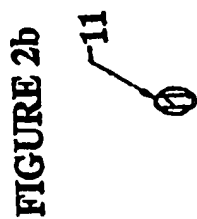
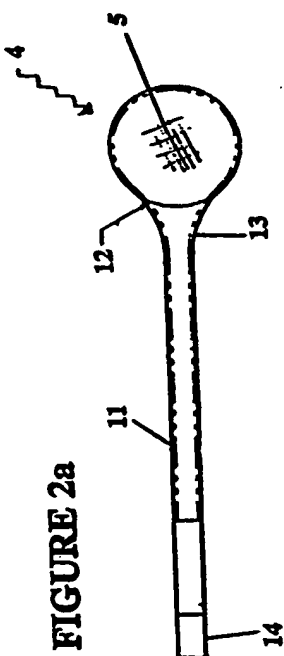
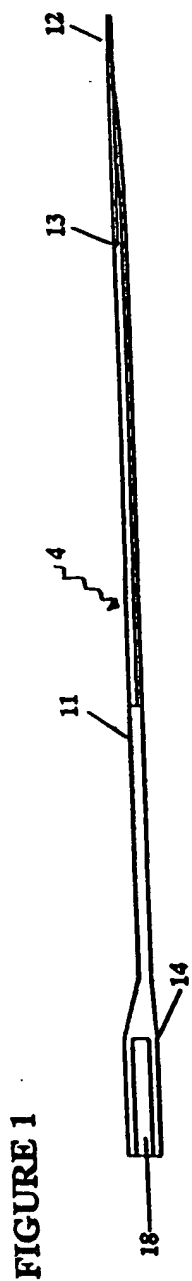


FIGURE 4

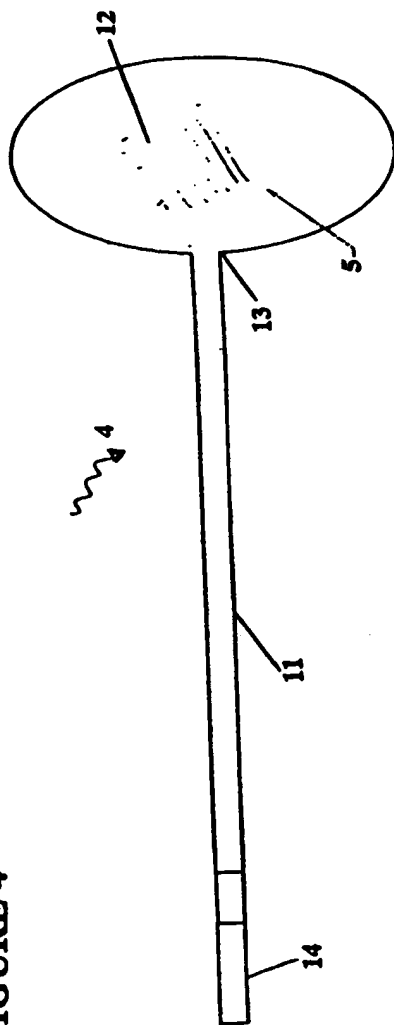
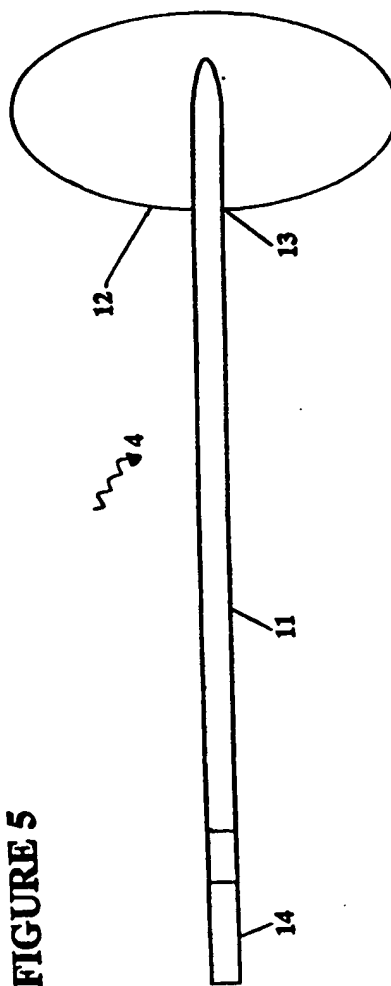


FIGURE 5



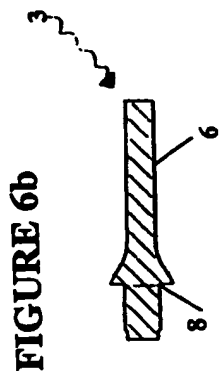
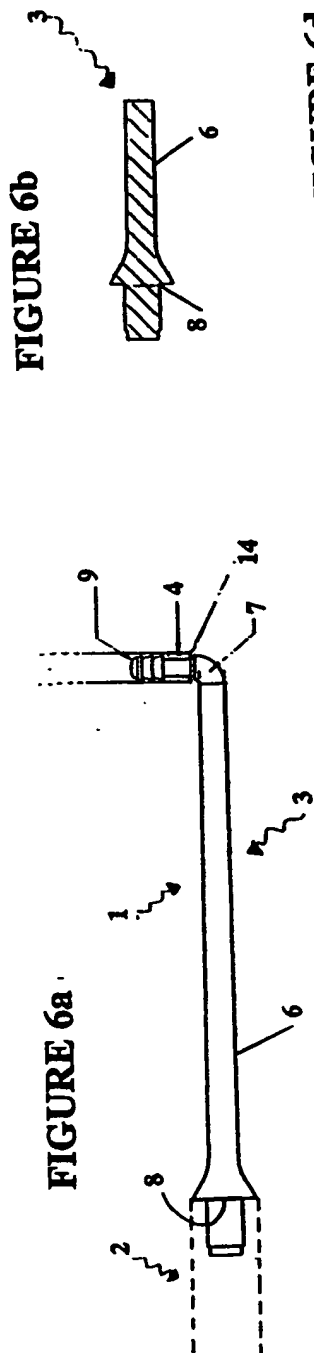


FIGURE 6d

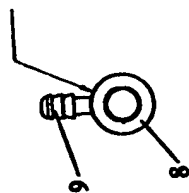


FIGURE 6e

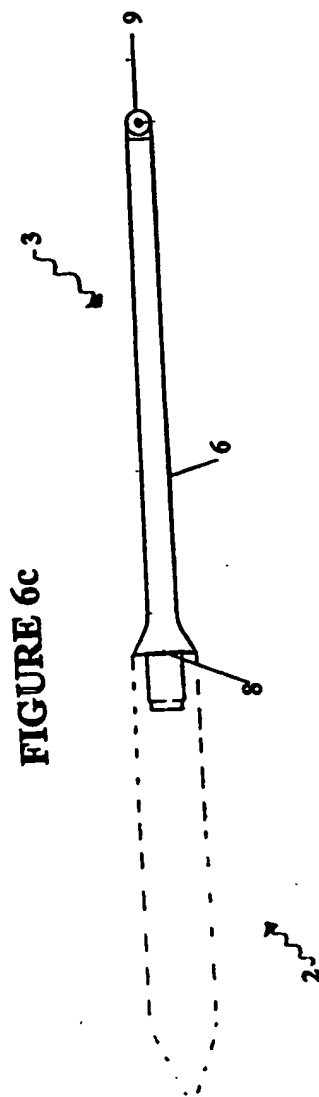
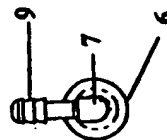


FIGURE 7

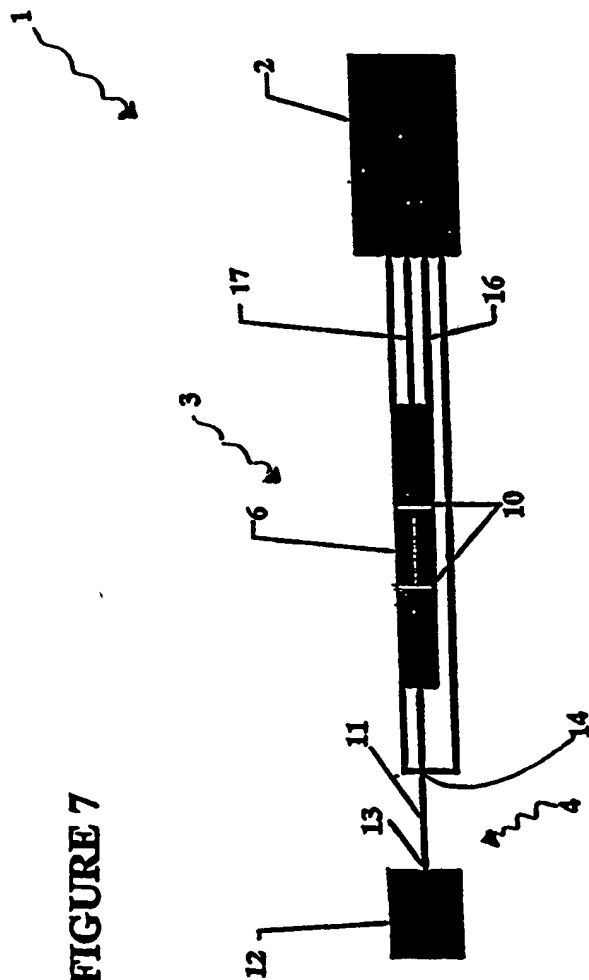


FIGURE 7b

